

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the Application of

Andrés RIVERA et al.

On Appeal from Group: 1700

Application No.: 09/353,592

Examiner: S. Hon

Filed: July 15, 1999

Docket No.: 101054

For: APPLICATOR FOR A POLYMERIZABLE MONOMER

APPEAL BRIEF TRANSMITTALDirector of the U.S. Patent and Trademark Office
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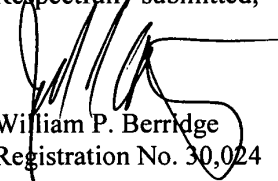
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For the convenience of the Finance Division, two additional copies of this transmittal letter are attached.

Respectfully submitted,


William P. Berridge
Registration No. 30,024Joel S. Armstrong
Registration No. 36,430

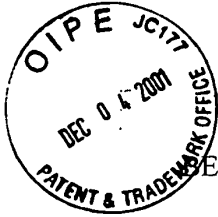
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OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, Virginia 22320
Telephone: (703) 836-6400

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BRIEF ON APPEAL

Appeal from Group 1700

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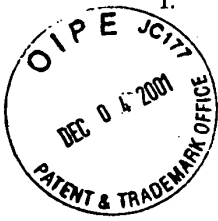
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OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, Virginia 22320
Telephone: (703) 836-6400
Attorneys for Appellants

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I. INTRODUCTION

This is an appeal from an Office Action mailed June 4, 2001, finally rejecting claims 1-30 of the above-identified patent application. No claims are allowed.

A. Real Party in Interest

The real party in interest for this appeal and the present application is Closure Medical Corporation, by way of an Assignment recorded in the U.S. Patent and Trademark Office at Reel 010102, Frame 0178.

B. Statement of Related Appeals and Interferences

There are presently no appeals or interferences, known to Appellant, Appellant's representative, or the Assignee, which will directly affect or be directly affected by or have a bearing upon the Board's decision in the pending appeal.

C. Status of Claims

Claims 1-30 are pending. Claims 1-30 are finally rejected and are on appeal. Claims 1-30 are set forth in the attached Appendix. Claims 1 and 24 are independent. Claims 2-23 and 28-30 directly or indirectly depend from claim 1; and claims 25-27 directly or indirectly depend from claim 24.

D. Status of Amendments

No Amendment After Final Rejection has been filed. Applicant requested reconsideration in response to the Final Office Action dated June 4, 2001, on August 28, 2001. By an Advisory Action dated September 19, 2001, it was indicated that the rejections were maintained.

II. THE INVENTION

The claimed invention is directed to new and improved applicator devices for applying a polymerizable or cross-linkable material, such as a cyanoacrylate adhesive, to a substrate. Page 1, lines 4-7. The invention in particular relates to such new and improved

applicators that allow for more precise control of the polymerization and/or cross-linking rate and/or extent of the material, by providing for alternative locations of an initiator or rate modifier with respect to the polymerizable or cross-linkable material. Page 5, lines 21-29.

The claimed invention achieves these and other advantages, including controlling the molecular weight of the polymerized or cross-linked material, controlling the setting time of the polymerized or cross-linked material, providing precision and convenience in applying the material to a substrate, extending the material shelf life, reducing the presence of residual monomer and avoid associated monomer odors, and controlling the flow properties of applied materials. Page 6, lines 7-17.

The claimed invention achieves these advantages by providing an applicator that includes an outer container and an inner container disposed within the outer container, where the inner container contains the polymerizable or cross-linkable material. A rate modifier for the polymerizable or cross-linkable material is disposed on an outer surface of the inner container. Page 5, line 30 to page 6, line 4.

More specifically, the claimed invention is directed to an applicator for dispensing a polymerizable or cross-linkable material, comprising: an outer container; an inner container disposed within said outer container, said inner container containing a polymerizable or cross-linkable material; and a rate modifier for said polymerizable or cross-linkable material disposed on an outer surface of said inner container. Claim 1. The claimed invention is also directed to a method of making an applicator for dispensing a polymerizable or cross-linkable material, comprising: sealing a polymerizable or cross-linkable material in an inner container; applying a rate modifier for said polymerizable or cross-linkable material to an outer surface of said inner container; and disposing said inner container within an outer container having dispensing means for dispensing said polymerizable or cross-linkable material from said applicator. Claim 24.

III. THE APPLIED REFERENCES

The applied reference is U.S. Patent No. 5,928,611 to Leung (hereafter, "Leung").

IV. ISSUES

The only issue on appeal is whether claims 1-30 would have been obvious under 35 U.S.C. §103(a) over Leung.¹

V. GROUPING OF CLAIMS

Each claim of this patent application is separately patentable, and upon issuance of a patent will be entitled to a separate presumption of validity under 35 U.S.C. §282. For convenience in handling of this appeal, all of the claims will be grouped and argued together. Thus, pursuant to 37 C.F.R. §1.192(c)(7), in this Appeal, the rejected claims stand or fall together.

VI. ARGUMENT

The Examiner rejects claims 1-30 over Leung. However, in the rejection, the Examiner has consistently improperly applied the law relating to obviousness, and has failed to establish even a prima facie case of obviousness. Further, the Examiner improperly construes the disclosure of Leung in arguing what would have been obvious over that disclosure. Proper application of the law and consideration of the cited reference demonstrates that no prima facie case of obviousness has been shown.

A. Factual Inquiries to Determine Obviousness/Non-Obviousness

Several basic factual inquiries must be made in order to determine obviousness or non-obviousness of claims of a patent application under 35 U.S.C. §103. These factual inquiries are set forth in Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966):

¹ Although the Examiner separately states two rejections, one of claims 1-14 and 16-23 and another of claim 15, both rejections rely only on Leung, and so they are treated together herein..

Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or non-obviousness of the subject matter is determined.

383 U.S. at 17-18, 148 USPQ at 467.

The specific factual inquiries set forth in Graham have not been considered or properly applied by the Examiner in formulating the rejection of the subject claims. Particularly, the scope and content of the prior art and the level of ordinary skill in the pertinent art were not properly determined and demonstrated and applied to the claimed invention.

In the present case, proper consideration of the factual inquiries demonstrates nonobviousness of the claimed invention. The cited reference does not teach or suggest the claimed applicator or method of making such an applicator.

B. Leung Does Not Teach or Suggest the Claimed Invention

Independent claim 1, representative of the claimed invention, is directed to an applicator for dispensing a polymerizable or cross-linkable material, comprising: an outer container; an inner container disposed within said outer container, said inner container containing a polymerizable or cross-linkable material; and a rate modifier for said polymerizable or cross-linkable material disposed on an outer surface of said inner container. Leung would not have rendered obvious the claimed invention, because Leung fails to teach or suggest each and every limitation of the claimed invention. In particular, Leung fails to teach or suggest at least the limitation that a rate modifier for the polymerizable or cross-linkable material is disposed on an outer surface of said inner container.

Similar to the claimed invention, Leung is directed to an applicator for dispensing a synthetic or semi-synthetic polymerizable or cross-linkable monomer material. According to Leung, the applicator comprises an applicator tip comprising a solid support having a polymerization or cross-linking accelerator or initiator for the synthetic or semi-synthetic

monomer material disposed thereon or therein, and a container body. The synthetic or semi-synthetic monomer material is located in the container body in a non-contacting relationship with the tip prior to dispensing the material. See Leung at Abstract and claim 1. For example, an embodiment of the disclosed applicator is shown in Leung Figure 3. According to Figure 3, the applicator of Leung includes an outer container 200 and an inner container 400 that contains an amount of monomer material 300 therein. According to this embodiment, the applicator tip 500 has the polymerization or cross-linking accelerator or initiator for the monomer material disposed therein or thereon. See also Leung at column 7, line 66 to column 8, line 4.

Leung also discloses several modification of the disclosed applicator. For example, Leung discloses that the polymerization or cross-linking accelerator or initiator can be located in the applicator at a position other than being loaded in or on the applicator tip. For example, at column 10, lines 43-53, Leung teaches that the accelerator or initiator may be stored in a separate compartment within the outer container 200 separate from the polymerizable or cross-linkable monomer material. Alternatively, in the same passage, Leung discloses that "the applicator container may be lined or coated with the initiator ... for example, in the device of FIG. 3, the initiator may be coated on the internal surface of body 200."

Although Leung discloses these modifications of the disclosed applicator, Leung does not teach or suggest all of the limitations of the claimed invention. In particular, Leung at most discloses that the accelerator or initiator may be lined or coated on the internal surface of the outer container 200. However, this disclosure is entirely different from the limitation of independent claims 1 and 24 that the rate modifier for the polymerizable or cross-linkable material is disposed on an outer surface of the inner container. For example, with reference

to Figure 1 of the present application, the rate modifier 50 according to the claimed invention is lined or coated on the outer surface of the inner container 40.

In order to have rendered obvious the claimed invention, the cited reference must teach or suggest each and every limitation of the claimed invention. See, for example, MPEP §2143, which specifies the requirements for a prima facie case of obviousness. However, in the present case, Leung fails to teach or suggest modifying the disclosed applicators so as to arrive at the claimed invention. Leung fails to teach or suggest an applicator, or a method of making an applicator, where a rate modifier for the polymerizable or cross-linkable material is applied to an outer surface of the inner container. Nowhere does Leung teach or suggest this limitation, nor does Leung teach or suggest that a method of making the applicator could or should be modified so as to arrive at the claimed invention.

C. The Examiner's Interpretation of Leung is Incorrect

In an effort to overcome the above-described deficiencies of Leung, the Examiner attempts to rely upon a clearly improper interpretation of the reference. In particular, the Examiner relies entirely on the disclosure at column 10, lines 47-53, that "the applicator container may be lined or coated with the initiator ... for example, in the device of FIG. 3, the initiator may be coated on the internal surface of body 200." However, the Examiner's interpretation is unsupported by the clear disclosure of Leung, is in fact contradictory to the disclosure of Leung, and is based at most on a hindsight reconstruction of the claimed invention.

The Examiner argues that the phrase "lined or coated" in Leung must be given two separate and distinct meanings. That is, the Examiner asserts that the phrase "lined or coated" must be given two separate and distinct meanings -- one for "lined" and one for "coated" -- rather than the understood meaning of both terms referring to the same single disclosure. The Examiner argues that one of ordinary skill in the art would understand the phrase to mean that

the accelerator or initiator may be coated on the outer surface of the inner container or lined on an inner surface of the outer container. See Final Office Action at page 3, first paragraph. Applicants disagree.

1. The Examiner's Interpretation is Unsupported by Leung

The Examiner argues that the phrase "lined or coated" must be given two distinct meanings, and would be so understood by one of ordinary skill in the art. However, Leung does not support this interpretation, and the Examiner has not demonstrated why one of ordinary skill in the art would so interpret the phrase.

As used in Leung, the phrase "lined or coated" was not used, and would not be understood by one of ordinary skill in the art to mean, two alternative embodiments. Rather, the phrase merely used two interchangeable words to mean the same embodiment. "Coat" is defined as ". . . 3. A layer of material covering something else; coating." American Heritage Dictionary, Second College Edition, p. 285 (1991). Likewise, "line" is defined as "line² . . . to fit a covering to the inside surface of . . . to cover the inner surface of." American Heritage Dictionary, Second College Edition, p. 733 (1991). (Copies of the dictionary definitions were previously made of record by Applicants.) Thus, both words refer to a layer or covering applied to another surface, i.e., the inner surface of the outer container.

In response, the Examiner argues that the phrase must be read as alternative embodiments. However, the disclosure of Leung fails to include such alternative embodiments. In particular, the only embodiment disclosed in Leung is the embodiment where the initiator is disposed on the inner surface of the outer container. See col. 10, lines 43-53. Nowhere does Leung teach or suggest that the initiator should instead be disposed on the outer surface of the inner container, as claimed.

2. Leung Expressly Refutes The Examiner's Interpretation

As described above, the Examiner argues that "lined" and "coated" must be given distinct meanings, because they are different words. The Examiner relies on the above-quoted definitions for the assertion that while Leung specifically discloses "lining" the initiator on the inner surface of the outer container, it would have been obvious to instead "coat" the initiator on the outer surface of the inner container, as claimed. This is incorrect and is contrary to the express disclosure of Leung.

As used in Leung, the words "lined" and "coated" are used in conjunction with reference to the outer container. Leung specifically recites that "the applicator container may be lined or coated with the initiator" (col. 10, lines 47-48, emphasis added). Thus, Leung uses the words "lined" and "coated" as referring only to the outer (applicator) container. Nowhere does Leung use the words or phrase "lined or coated," either together or individually, with respect to the inner container, or even imply that one of "lined" or "coated" was used with respect to the inner container.

Furthermore, to the extent that the Examiner argues that "coated" must refer to the inner container and "lined" must refer to the outer container, this interpretation is also specifically contrary to the disclosure of Leung. As described above, Leung only discloses that "the applicator container may be lined or coated with the initiator" (col. 10, lines 47-48, emphasis added). However, Leung goes further, by specifically disclosing that "in the device of FIG. 3, the initiator may be coated on the internal surface of body 200" (col. 10, lines 51-53, emphasis added). Leung thus explicitly uses the word "coated" in the same manner as the conventional definition for "lined" described above. This use in Leung thus clearly demonstrates that the words "lined" and "coated" were used as two words referring to the same disclosure, of applying initiator only to the inner surface of the outer container.

Thus, one of ordinary skill in the art would readily understand that both words referred to placing the initiator in the inner surface of the outer container, and not to placing the initiator on the outer surface of the inner container, as claimed. Any interpretation to the contrary is inconsistent with the disclosure of Leung, and is thus improper.

3. The Examiner Position Is Based Entirely On Hindsight

It is clear that the only motivation for modifying Leung to arrive at the claimed invention, or for interpreting the disclosure of Leung as asserted by the Examiner, derives only from the instant application. One of ordinary skill in the art would not have interpreted the recited phrase of Leung to have rendered obvious the claimed invention in the absence of the present disclosure.

However, this approach as a basis for an obviousness rejection is improper. The reason, suggestion or motivation for modifying a reference "can not come from the applicant's invention itself." In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). That is, the motivation for modifying the embodiments of Leung can not be a product of hindsight reconstruction of the claimed invention based on applicant's own disclosure.

Leung does not teach or suggest the instant claim limitation of applying a rate modifier for the polymerizable or cross-linkable material to an outer surface of the inner container. Although Leung discloses various embodiments of an applicator for applying a monomer material, those embodiments are different from and would not have rendered obvious the claimed invention. In the disclosed applicator of Leung, the accelerator or initiator for the monomer material is described as being loaded in or on an applicator tip, or being disposed on an inner surface of the outer container of the applicator. However, Leung fails to teach or suggest applying the rate modifier (initiator or accelerator) to an outer surface of the inner container.

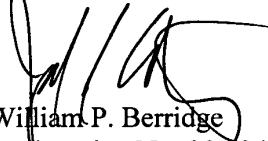
D. Conclusion

Accordingly, Leung fails to teach or suggest each and every limitation of the claimed invention. The claimed invention would thus not have been obvious over the disclosure of Leung.

VII. CONCLUSION

For all of the reasons discussed above, it is respectfully submitted that claims 1-30 define patentable subject matter under 35 U.S.C. §103(a) over the cited reference, and are thus in condition for allowance. For all of the above reasons, Appellants respectfully request this Honorable Board to reverse the rejections of claims 1-30.

Respectfully submitted,



William P. Berridge
Registration No. 30,024

Joel S. Armstrong
Registration No. 36,430

WPB:JSA

OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, Virginia 22320
Telephone: (703) 836-6400

Filed: December 4, 2001

APPENDIX

CLAIMS:

1. An applicator for dispensing a polymerizable or cross-linkable material, comprising:
 - an outer container;
 - an inner container disposed within said outer container, said inner container containing a polymerizable or cross-linkable material; and
 - a rate modifier for said polymerizable or cross-linkable material disposed on an outer surface of said inner container.
2. The applicator according to claim 1, wherein said outer container is flexible.
3. The applicator according to claim 1, wherein said outer container is a hollow, flexible cylinder.
4. The applicator according to claim 1, wherein said inner container is a frangible vial.
5. The applicator according to claim 4, wherein said frangible vial is made of glass or ceramic.
6. The applicator according to claim 1, wherein said rate modifier is in a non-contacting relationship with said polymerizable or cross-linkable material prior to opening of said inner container.
7. The applicator according to claim 1, wherein said rate modifier is lined or coated on said outer surface of said inner container.
8. The applicator according to claim 1, wherein said rate modifier is chemically bonded to said outer surface of said inner container.
9. The applicator according to claim 1, wherein said applicator is a syringe, a flexible cylinder, a tube, a pipette or an eye dropper.

10. The applicator according to claim 1, wherein said rate modifier comprises a detergent.
11. The applicator according to claim 1, wherein said rate modifier contains at least one member selected from the group consisting of a surfactant and an emulsifier.
12. The applicator according to claim 1, wherein said rate modifier is a polysorbate surfactant.
13. The applicator according to claim 1, wherein said rate modifier is a cationic surfactant.
14. The applicator according to claim 1, wherein said polymerizable or cross-linkable material is inorganic material or a combination of organic and inorganic materials.
15. The applicator according to claim 14, wherein said polymerizable or cross-linkable material is inorganic material selected from the group consisting of siloxanes, silicones, polysulfides, and polyphosphazenes.
16. The applicator according to claim 1, wherein said polymerizable or cross-linkable material is synthetic material selected from the group consisting of monomers that produce thermoplastic and thermoplastic elastomer polymers.
17. The applicator according to claim 16, wherein said polymers are selected from the group consisting of polyamides, nylon, polyvinylchloride, polycarbonates, polyethylene, polystyrene, polypropylene, fluorocarbon resins, polyurethane resins, acrylate resins and polyesters.
18. The applicator according to claim 1, wherein said polymerizable or cross-linkable material comprises 1,1-disubstituted ethylene monomer.
19. The applicator according to claim 18, wherein said monomer comprises an alpha-cyanoacrylate monomer.

20. The applicator according to claim 1, wherein said rate modifier is selected from the group consisting of alkylbenzyltrimethylammonium chloride, tetrabutylammonium bromide, sodium tetradecyl sulfate, dodecyltrimethyl(3-sulfopropyl)ammonium hydroxide, imidazole, tryptamine, urea, arginine, povidone, phosphines, triethyl phosphite, phosphonium salts, methyl gallate, ascorbic acid, tannic acid, sodium bisulfite, magnesium hydroxide, calcium sulfate, sodium silicate, thiourea, polysulfides, monensin, nonactin, calixarenes, polymeric epoxides, carbonates, cobalt naphthenate, manganese acetylacetonate and phase transfer catalysts.

21. The applicator of claim 1, wherein said polymerizable or cross-linkable material is organic.

22. The applicator of claim 1, wherein said rate modifier is a catalyst.

23. The applicator of claim 1, wherein the polymerizable or cross-linkable material is biocompatible.

24. A method of making an applicator for dispensing a polymerizable or cross-linkable material, comprising:

sealing a polymerizable or cross-linkable material in an inner container;

applying a rate modifier for said polymerizable or cross-linkable material to an outer surface of said inner container; and

disposing said inner container within an outer container having dispensing means for dispensing said polymerizable or cross-linkable material from said applicator.

25. The method according to claim 24, wherein said sealing step comprises sealing said polymerizable or cross-linkable material in a frangible vial.

26. The method according to claim 24, wherein said applying step comprises coating or lining an entire surface of said outer surface of said inner container with said rate modifier.

27. The method according to claim 24, wherein said applying step comprises coating or lining only a part of said outer surface of said inner container with said rate modifier.

28. A method of applying a polymerizable or cross-linkable material to a substrate, comprising:

providing an applicator according to claim 1;

opening said inner container of said dispenser to contact said polymerizable or cross-linkable material with said rate modifier; and

dispensing said polymerizable or cross-linkable material from said outer container.

29. The method of claim 28, wherein said inner container is a frangible vial, and said opening step comprises breaking said frangible vial.

30. The method of claim 28, wherein said dispensing step comprises squeezing said outer container to dispense said polymerizable or cross-linkable material.